PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference JNR/PG4886C	**FOR FURTHER ACTION** See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP 03/08144	International filing date *(day/month/year)* 23.07.2003	Priority date *(day/month/year)* 25.07.2002
International Patent Classification (IPC) or both national classification and IPC A61M15/00		
Applicant GLAXO GROUP LIMITED et Al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand 27.01.2004	Date of completion of this report 14.05.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Kroeders, M Telephone No. +31 70 340-1967

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/08144

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-45 as originally filed

Claims, Numbers

1-23 as originally filed

Drawings, Sheets

1/7-7/7 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 23

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 23

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	-
	No:	Claims	1-22
Inventive step (IS)	Yes:	Claims	-
	No:	Claims	1-22
Industrial applicability (IA)	Yes:	Claims	1-22
	No:	Claims	-

2. Citations and explanations

   see separate sheet

Re Item III
Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 23 was not searched in view of Article 17(2)(a)(i) PCT and Rule 39.1(iv) PCT and therefore no substantive examination can be performed.
Moreover, claim 23 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated on the subject-matter of this claim (Article 34(4)(a)(i) PCT).

Re Item V
Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The subject-matter of claim 1 does not meet the requirements of Article 33(2) PCT

The document WO-A-0064519 discloses (the references in parentheses applying to this document):

> a medicament dispenser device for use in the delivery of a combination medicament product, the device comprising:
> a first medicament container (1) for containing a first medicament component;
> first release means (7b) for releasing the contents of said first medicament container (1);
> at least one further medicament container (2) for containing at least one further medicament component;
> at least one further release means (7a) for releasing the contents of each said at least one further medicament container (2); and
> mixing means for promoting the mixing of the released contents of the first and at least one further medicament container (page 4, lines 34 to 36 and figure 3d),
> wherein the first medicament component is kept separate from the at least one further medicament component until the point of release thereof for delivery in combination (page 4, lines 34 to 36).

The subject-matter of claim 1 is therefore not new (Article 33(2) PCT).
The above novelty objection also holds in view of documents US-A-5524613 (column 7,

34 to column 8, line 15), WO-A-0139823 (page 5, line 22 to page 9, line 15), US-A-5901883 (column 7, line 3 to column 8, line 48).

The device of claim 1 is industrially manufacturable and therefore meets the requirements of Article 33(4) PCT.

Dependent claims 2 to 22 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:

The features of claims 2 and 3, regarding when the mixing is to take place, are known from documents WO-A-0064519 (page 4, lines 34 to 36), US-A-5901883 (column 8, lines 23 to 27), and are therefore not new (Article 33(2) PCT).

The features of claims 4 to 14 appear to be consistent with features normally applied for the entrainment of the medicament. Any technical feature capable of entraining a powdered medicament will automatically affect in mixing a plurality of medicaments if they are administered simultaneously. Thus, it is considered that these features are disclosed in documents WO-A-0064519 (see e.g. figure 3d), US-A-5524613 (column 4, line 65 to column 5, line 16). These claims therefore do not meet the requirements of Articles 33(2) or (3) PCT.

The combination of two medicament components dispensed according to claims 15 and 18 to 22 are known from document WO-A-0064519 (page 4, lines 1 to 11). Claims 18 to 22 therefore do not meet the requirements of Article 33(2) PCT.

The actuation indicator disclosed in dependent claim 16 is a normal design feature in a medicament dispensing device. It's use is also disclosed in document WO-A-0064519 (page 8, lines 16 to 19), and is therefore not new (Article 33(2) PCT).

Dependent claim 17 does not meet the requirements of Article 6 PCT, as it contradicts the subject-matter of claim 1. The scope of claim 1 is clear in that the more than one medicament components are to be delivered **in combination** and are **mixed** to achieve that purpose. The wording of claim 17 leads to believe that the medicament components could be delivered separate. Therefore, the features of these two claims

are considered to be mutually exclusive. The wording of claim 17 has to reflect the intentions as formulated on description page 22, lines 25 - 31.
When evaluating this "timing control" according to the description, it is considered that a mechanical structure attempting to achieve a simultaneous release of the medicament components is, in fact, limiting/controlling the relative time of release. Such a feature is disclosed in document WO-A-0064519 (figure 1, feature 6), and is therefore not new (Article 33(2) PCT).

The following document is cited under Rule 70.10 PCT, as it constitutes prior art for the purposes of Article 33(2) PCT for claims 1 - 3, 5 - 10 and 13 - 22.

Certain published documents

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
WO-A-03061743	31-07-2003	22-01-2003	25-01-2002